Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0990131	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cardinal Hill Rehabilitation Hospital	2050 Versailles Road, Lexington, KY	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on staff interview and record review on 03/12/2020, the laboratory failed to perform quality assessment for the specialties of hematology, chemistry and microbiology from 04/11/18 through 03/11/2020. Quality Assessment was not performed using pre-analytical, analytical and post analytical metrics. Findings include: 1. Policy review on 03/12/2020 at 10:15 AM revealed the policy only identified one (1) of three (3) metrics required for quality assessment activities from 04 /11/18 through 03/11/2020. 2. Record review revealed there was one (1) post analytical metric monitored from 04/11/18 through 03/11/2020. Further review revealed there was no documented evidence that pre-analytical or analytical quality measures were monitored and documented. 3. An interview with the technical supervisor on 03/12/2020 at 10:15 AM revealed there was not a system in place from 04/11/18 through 03/11/2020 to monitor pre-analytical, analytical, and post-analytical metrics.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check

	the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview on 03/12/2020, the laboratory failed to perform two (2) sensitivity controls each day of patient testing from 04/11/18 through 03/11/2020. Findings include: 1. Review of quality control records on 03/12/2020 at 2: 20PM revealed sensitivity controls were tested one (1) day per week of patient testing on the Vitek analyzer. 2. Interview with the technical supervisor at 2:20 PM on 03/12 /2020 revealed the laboratory failed to have a system in place to ensure control organisms were tested each day of patient testing.